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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/512,515	02/24/00	DAS K	UMD-1.0-042

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1642	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/512,515	Applicant(s) DAS, KIRON M	
	Examiner Brenda G. Brumback	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *21-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-20 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the inventions of Groups I and II can be examined together without serious burden to the Examiner. This is not found persuasive because the inventions of the two groups not only have different method steps, different modes of operation, different functions, and different effects, but they also have separate and distinct classifications and require separate searches. For these reasons, examination of both groups together would constitute a serious burden to the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-29 are pending. Claims 21-29 are withdrawn from consideration as directed to a nonelected invention. Claims 1-20 are pending and under examination.

Specification

3. The disclosure is objected to because of the following informality. The address of the American Type Culture Collection found on page 6 of the specification is incorrect, as the ATCC has relocated. The present address is 10801 University Blvd., Manassas, VA 20110-2209. Amendment of the disclosure to indicate the current address is required.

Claim Objections

4. Claim 2 is objected to because of the following informality. In line 2 of the claims "epithelial" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claims 3, 6, 7, 9, 11, 13, 16, 17, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 13 recite an antibody or fragment indirectly attached to a detectable label. While the disclosure teaches detectable labels which can be directly attached to the antibody (see pages 14-15), it fails to teach the meaning of indirect attachment of the detectable labels. Thus, the metes and bounds of the claimed invention cannot be determined and the claims are indefinite.

Claims 6, 7, 16, and 17 recite the limitation "the intestinal tissue" in line 2 or 3 of each of the claims. There is insufficient antecedent basis for this limitation in the claims because the base claims from which the claims depend recite gastric tissue, not intestinal tissue.

Claims 9 and 19 recite performing a further step of performing a negative control assay on a negative control sample to detect human gastric intestinal metaplasia cells present in the negative control sample. The methods of the base claims are drawn to detecting gastric intestinal metaplasia cells in a gastric tissue sample as a positive indication of disease, *i.e.*, the presence of

the cells indicates that the sample is positive. It is therefore unclear how a sample in which positive cells are detected can function as a negative control. Correction is required.

Claim 11 is drawn to an immunoassay method for screening for human gastric intestinal metaplasia, thereby indicating a predisposition for gastric carcinoma. It is unclear whether diagnosis of human gastric metaplasia is in and of itself indicative of a predisposition for gastric carcinoma or whether the indication of the predisposition is dependent upon immunoreactivity with monoclonal antibody DAS-1. Correction is required.

6. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diagnosing human gastric intestinal metaplasia of the incomplete or colonic type, does not reasonably provide enablement for diagnosing other gastric intestinal metaplasias. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue

experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claimed invention is drawn to an immunoassay for diagnosing human gastric intestinal metaplasia comprising contacting a gastric tissue sample with the monoclonal antibody DAS-1 which reacts with human gastric intestinal metaplasia antigen, wherein immunoreactivity indicates a positive diagnosis of human gastric intestinal metaplasia. Thus, the claimed invention encompasses general diagnosis of all types of human gastric intestinal metaplasia by immunoreactivity with the antibody.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that the monoclonal antibody DAS-1 reacts with only approximately 25% of cases of gastric intestinal metaplasia, not all cases. Furthermore, the art suggests that the monoclonal antibody

is selectively immunoreactive with the incomplete or colonic type of gastric intestinal metaplasia (see Griffel et al., Digestive Diseases and Sciences, 45(1):40-48, January 2000, the paragraph bridging pages 40 and 41 and page 41, first full paragraph).

The amount of direction or guidance present and the presence or absence of working examples: The specification discloses that the monoclonal antibody DAS-1 is immunoreactive with only about 35% of samples from patients with historically confirmed gastric intestinal metaplasia without gastric carcinoma (see page 7, lines 9-36, and, Example 1). The specification discloses that reactivity with monoclonal antibody DAS-1 helps identify those patients with gastric intestinal metaplasia who are at risk for gastric carcinoma (see page 8, lines 6-7). The working example (pages 21-22) discloses immunoreactivity of monoclonal DAS-1 with 94% of samples from gastric intestinal metaplasia samples from gastric carcinoma patients, but only 35% of samples from gastric intestinal metaplasia samples without gastric carcinoma. The disclosure teaches that monoclonal antibody DAS-1 is immunoreactive with a subset of gastric intestinal metaplasia, that of the colonic phenotype, and is not immunoreactive with other cases.

The breadth of the claims and the quantity of experimentation needed: Because both the art and the specification disclose that the monoclonal antibody DAS-1 is immunoreactive with samples from only a specific subset of patients with gastric intestinal metaplasia, the incomplete or colonic phenotype, and because the claims are drawn to general diagnosis of human gastric intestinal metaplasia of any type, the skilled artisan would be unable to practice the claimed method commensurate in scope with the claims absent undue experimentation.

7. Claims 6-8 and 16-20 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The nature of the invention: The claimed invention is drawn to a method of diagnosing human gastric intestinal metaplasia comprising deparaffinizing intestinal tissue and reacting the tissue with monoclonal antibody, DAS-1.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that the monoclonal antibody DAS-1 specifically reacts with normal colonic epithelial cells (which are cells from "intestinal" tissue; see Gujral et al., Gastroenterology 106/4, Part 2, April 1994).

The amount of direction or guidance present and the presence or absence of working examples: The specification discloses that monoclonal antibody DAS-1 reacts sensitively and specifically with normal colonic epithelium (see page 7, lines 14-18, and page 8, lines 20-23). The specification does not teach that reactivity of intestinal or colonic tissue with the monoclonal antibody DAS-1 is diagnostic of human gastric intestinal metaplasia. The single working example is drawn to immunoreactivity of DAS-1 with gastric tissue samples, not intestinal tissue samples, as diagnostic of incomplete or colonic gastric intestinal metaplasia (pages 21-22).

The breadth of the claims and the quantity of experimentation needed: Since both the art and the specification disclose that the monoclonal antibody DAS-1 reacts with normal colonic

(intestinal) epithelium, one of skill in the art would be unable to practice the claimed invention, which is drawn to immunoperoxidase staining of intestinal tissue with the monoclonal antibody DAS-1 in order to diagnose gastric intestinal metaplasia, absent undue experimentation.

8. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not set forth in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the deposit of the hybridoma ATCC accession number HB 9397. While the specification provides enough information for one of skill in the art to produce a hybridoma with the same or similar properties as hybridoma ATCC accession number HB 9397, reproduction of an identical hybridoma is an unpredictable event. Because the claims specially require the use of the monoclonal antibody DAS-1 produced by hybridoma ATCC accession number HB 9397, evidence must be provided that hybridoma ATCC accession number HB 9397 is readily available to the public. It is not clear from the disclosure that deposits of hybridoma ATCC accession number HB 9397 meet all the criteria set forth in MPEP 608/01 (p)(C), items 1-3. Assurance of compliance may be in the form of a declaration or averment under oath. A suggested format for such a declaration or averment is outlined as follows:

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that ensure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 35 CFR 1.14 and 35 USC 122.

6. States that the deposited material will be stored with all care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case at least thirty (30) years after the date of a deposit or for the enforceable life of the patent, whichever is longer.

7. Acknowledges the duty to replace the deposit should the depository be unable to furnish a sample when requested due to the condition of the deposit.

8. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like are punishable by fine or imprisonment, or both,

under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

As a possible means of completing the record, applicants may submit a copy of the deposit receipt.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

a. Claims 1, 3-5, 9-11, and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Garewal et al. (Gastroenterology 112 (4 SUPPL.):pA567, 1997)

The claimed invention is drawn to a method of diagnosing human gastric intestinal metaplasia comprising contacting a gastric tissue sample with the monoclonal antibody DAS-1 and detecting immunoreactivity; wherein the antibody is attached to a detectable label; wherein the detecting is performed by immunoperoxidase stain, immunofluorescence, immunoelectronmicroscopy, or ELISA; wherein positive and negative controls are run with the

method; and wherein immunoreactivity in the sample indicates a predisposition for gastric carcinoma in the patient.

Garewal et al. teach a method for detecting incomplete type of gastric intestinal metaplasia comprising staining gastric cardia biopsy tissues by immunoperoxidase using monoclonal antibody DAS-1. Garewal et al. teach staining normal gastric cardia tissue and samples showing gastric intestinal metaplasia as a negative and positive controls. Lastly, Garewal et al. teach that incomplete gastric intestinal metaplasia is the type that is associated with gastric adenocarcinoma.

b. Claims 1-5 and 9-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Griffel et al.

The claimed invention is drawn to a method of diagnosing human gastric intestinal metaplasia comprising contacting a gastric tissue sample with the monoclonal antibody DAS-1, which reacts with colonic epithelial specific protein, and detecting immunoreactivity; wherein the antibody is attached to a detectable label; wherein the detecting is performed by immunoperoxidase stain, immunofluorescence, immunoelectronmicroscopy, or ELISA; wherein positive and negative controls are run; and wherein immunoreactivity in the sample indicates a predisposition for gastric carcinoma in the patient.

Griffel et al. teach a method for diagnosing Barrett's esophagus by immunoperoxidase staining comprising contacting gastric cardia biopsy tissue with the monoclonal antibody DAS-1,

which reacts with colonic epithelial specific protein, and rabbit anti-mouse antibody conjugated to peroxidase (see page 40, abstract and last partial paragraph of the page, and pages 41-42, Materials and Methods). Griffel et al. teach that the monoclonal antibody is immunoreactive with the colonic type of intestinal metaplasia (see page 41, first full paragraph), but not with normal gastric tissue. Griffel et al. teach staining biopsy samples taken from cases of histologically confirmed Barrett's esophagus and from samples of normal morphology without intestinal metaplasia as positive and negative controls.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

a. Claims 2 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garewal et al. in view of Badve et al. (Hepatology 28/4:523A, Nov. 1998).

The claimed invention is drawn to a method of diagnosing human gastric intestinal metaplasia comprising contacting a gastric tissue sample with the monoclonal antibody DAS-1, which reacts with colonic epithelial specific protein, and detecting immunoreactivity, wherein immunoreactivity in the sample indicates a predisposition for gastric carcinoma in the patient.

As set forth *supra*, Garewal et al. teach diagnosing incomplete type of gastric intestinal metaplasia by staining gastric cardia biopsy tissues using immunoperoxidase with monoclonal antibody DAS-1. Garewal does not teach the specific antigen present in the tissue with which the monoclonal antibody reacts.

Badve et al. teach that monoclonal antibody DAS-1 is immunoreactive with a specific colonic epithelial protein.

One of ordinary skill in the art at the time the invention was made would have found it *prima facie* obvious to have stained a gastric tissue sample for colonic epithelial specific protein as diagnostic of incomplete type of gastric intestinal metaplasia because Garewal et al. teach that the antibody is diagnostic of incomplete type of gastric intestinal metaplasia and Badve et al. teach that the specific immunoreactivity of the antibody is to a specific protein in the colonic epithelium.

b. Claims 1-6, 8-16, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Garewal et al. in view of Badve et al., or Griffel et al., as applied to claims 1-5 and 9-15 above, and further in view of Pantuck et al. (British Journal of Urology 82:426-430), Babaev et al. (Database Medline on Dialog, 03905999, Arkhiv Patolgii, 45/1:76-78, 1983), and Petersen et al. (Database Medline on Dialog, 05813907, Journal of Histochemistry and Cytochemistry 34/6:801-809, June 1986).

The claimed invention is drawn to a method of diagnosing human gastric intestinal metaplasia comprising contacting a gastric tissue sample with the monoclonal antibody DAS-1, which reacts with colonic epithelial specific protein and detecting immunoreactivity; wherein the antibody is attached to a detectable label; wherein the detecting is performed by a method selected from the immunoperoxidase stain, among others; wherein positive and negative controls are run with the method; and wherein immunoreactivity in the sample indicates a predisposition for gastric carcinoma in the patient. Dependent claims recite the steps of deparaffinizing the tissue by heating; immersing the tissue in xylene; rehydrating the tissue in decreasing concentrations of alcohol at 100%, 95%, 70%, and 50%; washing in PBS, reducing the aldehydes; reacting the tissue with normal goat serum, the monoclonal antibody DAS-1, biotinylated goat anti-mouse antibody, and avidin-biotin-peroxidase complex; treating with diaminobenzidine; washing; staining with hematoxylin or eosin or both (H&E); and examining the stained tissue under a microscope to detect immunoreactivity.

As set forth *supra*, either of Garewal et al. in view of Badve et al., or Griffel et al., teach a method for staining gastric biopsy tissue by immunoperoxidase using the monoclonal antibody DAS-1 and an anti-mouse antibody conjugated to peroxidase for diagnosis of the colonic type of intestinal metaplasia. Griffel et al. teaches heating the slides; rehydrating the slides with xylene and decreasing concentrations of alcohol at 100% and 80%; washing in PBS; contacting the slides with $NaBH_4$; reacting the tissue with the monoclonal antibody, an anti-mouse antibody conjugated to biotin, and streptavidin peroxidase; treating with diaminobenzidine, washing, and

staining with H&E (see the paragraph bridging pages 41 and 42). Neither Garewal et al. in view of Badve et al. nor Griffel et al. teach reacting the tissue with normal goat serum, incubating with a goat anti-mouse antibody, or a graded alcohol series of 100%, 95%, 70%, and 50% for rehydration.

Pantuck et al. teach a method of staining paraffin-embedded tissue specimens with the monoclonal antibody $7E_{12}H_{12}$ (which the specification teaches is an alternative name for DAS-1; see page 7, line 14) comprising heating the slides to deparaffinize the tissue, immersing the slides in xylene; rehydrating the slides with decreasing concentrations of alcohol at 100%, 95%, and 80%; washing in PBS; reducing the free aldehydes with $NaBH_4$; reacting the tissue with the monoclonal antibody, an anti-mouse antibody conjugated to to biotin, and streptavidin peroxidase; treating with diaminobenzidine, washing, and staining with H&E (see the paragraph bridging pages 41 and 42).

Babaev et al. teach that incubation of paraffin sections with normal goat serum decreases nonspecific staining.

Petersen et al. teach goat anti-mouse antibody conjugated to peroxidase as the secondary antibody in an immunoperoxidase staining method.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used normal goat serum to reduce nonspecific staining in the method taught by either Garewal et al. in view of Badve et al. or Griffel et al. for reduction of nonspecific staining and to have used goat anti-mouse antibody as the secondary antibody in the method of

Garewal in view of Badve et al. or as an equivalent of the rabbit anti-mouse antibody diclosed by Griffel et al. One of ordinary skill in the art at the time the invention was made would have found it *prima facie* obvious to have rehydrated the tissue in decreasing concentrations of alcohol, as is taught by Pantuck et al. Although Pantuck et al. teach 100%, 95%, and 80% as the gradient alcohol solutions, absent some evidence to the contrary, the claimed gradients of 100%, 95%, 70% and 50% would be considered as equivalent to those of Pantuck et al.

c. Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Garewal et al. and Badve et al., or Griffel et al., in view of Pantuck et al., Babaev et al., and Petersen et al. as applied to claims 1-6, 8-16, and 18-20 above and further in view of Pinkus et al. (Database Medline on Dialog, 06042776, Journal of Histochemistry and Cytochemistry, 33/5:465-473, May 1985).

The claimed method is as described above further comprising trypsinizing the tissue before reacting the tissue with the goat serum and monoclonal antibody. None of Garewal et al., Badve et al., Griffel et al., Pantuck et al., Babaev et al., or Petersen et al. teach reacting the tissue with trypsin prior to addition of the antibodies.

Pinkus et al. teach that preliminary trypsinization of formalin-fixed paraffin-embedded tissues ensures optimal reactivity of monoclonal antibodies with the target antigens in immunoperoxidase techniques.

One of ordinary skill in the art at the time the invention was made would have found it *prima facie* obvious to have added a trypsinization step to the method of either Garewal et al. and Badve et al., or Griffel et al., in view of Pantuck et al., Babaev et al., and Petersen et al., as taught by Pinkus et al., in order to ensure optimal reactivity of the DAS-1 monoclonal antibody with the target antigen in paraffin-embedded gastric tissue.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB
September 11, 2001

Brenda Brumback
Brenda Brumback,
Patent Examiner